REMARKS

Claims 32-57, 60 and 61 are pending in this application. Claims 37, 39, 46 and 48-51 have been withdrawn from consideration. Claims 32-36, 38, 40-45, 47, 52-57 and 60-61 have been rejected. Claims 40 and 47 have been amended. Claim 57 has been canceled. No new matter has been added by this amendment. Reconsideration is respectfully requested in light of the following remarks.

I. Species Election

Applicants' arguments regarding the election of species have not been found persuasive. Claims 37, 39, 46, 48-49, and 50-51 have been withdrawn from further consideration as being drawn to a nonelected invention.

II. Objections to the Claims

Claim 57 has been objected to as being of improper dependent form for failing to further limit the subject matter of a previous claim. Accordingly, Applicants have canceled claim 57.

Claim 32 has been objected to for use of the term "cased" rather than "case." In so far as claim 40, rather than claim 32, recites the term "cased," Applicants have amended claim 40 to correct this inadvertent typographical error.

In light of these amendments, it is respectfully requested that the objections to claims 57 and 32 be withdrawn.

III. Rejections Under 35 U.S.C. §112

Claims 45 and 47 have been rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicants regard as the invention. It is suggested that Applicants claim an active-ingredient-containing core of pellets. It is asserted that in claim 47 the active-ingredient core is inert with an active ingredient coating. The Office suggests that if the active-ingredient core is inert, it is unclear how the active ingredient core is thus still "active." The Office has interpreted claims 45 and 47 in light of the specification (more specifically paragraphs 92-96) as being directed toward an inert core comprising active ingredients which coat the inert core.

As the Office acknowledges, claim 47 is directed to an inert core which is covered by a coating containing active ingredients. Accordingly, in an earnest effort to clarify the present invention, Applicants have amended claim 47, as supported by paragraphs 94-96 of the Specification, to indicate that the pellets or micropellets comprise an inert core which is coated with an active-ingredient-containing coating. In light of this amendment, it is respectfully requested that this rejection be reconsidered and withdrawn.

IV. Rejections Under 35 U.S.C. §102

Claims 32-36, 38, 41, 43-45, 47, and 52-57 have been rejected under 35 U.S.C. 102(b) as being anticipated by Skinhoj et al. (US 2002/0034544). The Office suggests that Skinhoj et al. teach coatings which are made by mixing a polyaclylate dispersion (Eudragit NE30D) with magnesium

stearate (fatty acid salt) and silicates such as talc, wherein the aqueous dispersion can include Eudragit NE 30D or a mixture of acrylic resins, including Eudragit RL 30D and Eudragit RS 30D. The Office contends that the coatings are applied by spraying using a fluidized bed and that Skinhoj et al. teach multi-layer coatings with an inert core containing layers of active ingredient (midodrine), wherein the core can comprise coated pellets provided in multiple-unite dosage systems within capsules. It is further suggested that binders such as microcrystalline cellulose (auxiliary) can be incorporated with the active ingredient.

Claims 32-36, 38, 41, 43-45, 47, and 52-57 have been rejected under 35 U.S.C. 102(e) as being anticipated by Mulye et al. (2005/0129778). This reference is suggested to teach pharmaceutical coatings for beads, wherein said coatings contain controlled release polymers and an inert core. It is suggested that an inner layer contains the water-soluble drug and the outer contains a controlled release polymer, wherein the formulation may contain any other component mixed that is normally present in sustained release polymers. The Office suggests that examples of polymers used with Muyle et al. include polyacrylates such as mixtures of acrylic acid and methacrylate polymers, wherein the polymer can be in the form of an aqueous dispersion. The Office suggests that this reference teaches that coating layers may contain additional components such as a mixture of magnesium stearate and silicates such as talc or kaolin, wherein the formulations of Muyle et al. are sprayed onto inert beads using fluid bed coating machines. Mulye et al. is suggested to teach that auxiliaries such as binders are present with the drug, wherein examples of

suitable water soluble drugs include metoprolol tartate. Mulye et al. are also suggested to teach multiple unit dosage forms such as capsules containing beads (pellets).

Applicants respectfully traverse these rejections under 35 U.S.C. 102. The present invention is directed to a process for the preparation of an aqueous dispersion for the preparation of a coating, which comprises the steps of:

1. *pre-mixing* at least one fatty acid salt and at least one layer silicate to form a separating agent mixture, and

2. adding the separating agent mixture to an aqueous suspension of film-forming polymer(s).

In this respect, an inventive element of the claimed process is the step of pre-mixing at least one fatty acid salt with at least one layer silicate, prior to addition of the same to an aqueous suspension of film-forming polymer(s). Neither of the cited references teach or suggest the method as presently claimed.

In particular, Skinhoj et al. describe coatings and coating suspensions applied for such coatings, which are only characterized by their respective combinations. While para. [0359] of Skinhoj et al. suggests overcoming tackiness of a water-dispersible film-forming substance by incorporating an anti-adhesive such as magnesium stearate or talc, nowhere does this reference describe a process for the preparation of an aqueous dispersion for the preparation of a coating, which includes a pre-mixing step as presently claimed.

Similarly, while para. [0097] of Mulye et al. teaches anti-tacking agents such as stearates and talc, Muyle et al. fail to teach or suggest a process for preparing an aqueous

dispersion for the preparation of a coating, which includes a pre-mixing step as presently claimed.

To anticipate, the reference "must not only disclose all elements of the claim within the four corners of the document, but must also disclose those elements 'arranged as in the claim.'" *Net MoneyIN, Inc. v. VeriSign, Inc.*, 545 F.3d 1359, 1369 (Fed. Cir. 2008) (quoting *Connell v. Sears, Roebuck & Co.*, 722 F.2d 1542, 1548 (Fed. Cir. 1983)); see also, *e.g.*, *In re Arkley*, 455 F.2d 586, 587 (CCPA 1972) ("[The] reference must clearly and unequivocally disclose the claimed [invention] or direct those skilled in the art to the [invention] without any need for picking, choosing, and combining various disclosures not directly related to each other by the teachings of the cited reference").

Because Skinhoj et al. and Mulye et al. fail to describe a method which includes the step of pre-mixing at least one fatty acid salt with at least one layer silicate, prior to addition of the same to an aqueous suspension of film-forming polymer, these references cannot be held to anticipate the present invention. It is therefore respectfully requested that these rejections under 35 U.S.C. 102 be reconsidered and withdrawn.

V. Rejections Under 35 U.S.C. §103

Claims 32-36, 38, 41, 43-45, 47, 52-57 and 60-61 have been rejected under 35 U.S.C. 103(a) as being unpatentable over Mulye et al. (US 2005/0129778) and Lofroth et al. (US 2004/0030033). The teachings of Muyle et al. are as described above. It is acknowledged that Mulye et al. do not expressly teach metoprolol or metoprolol succinate. It is suggested, however, that Lofroth et al. teach dispersions of

acrylate polymers. The Office asserts that the beads of Lofroth et al. may contain inert cores of silicon dioxide, on which active ingredient such as metorpolol and metorpolol succinate is deposited. The Office concludes that it would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made to include metoprolol and metoprolol succinate into the formulations of Mulye et al. Regarding the amount of fatty acid salt present and the content of the layer silicate present, the Office suggests that it would have been within the purview of the skilled artisan to optimize the amounts of each component.

Applicants respectfully traverse this rejection. A proper obviousness determination requires that an Examiner make "a searching comparison of the claimed invention - *including all its limitations* - with the teaching of the prior art." *See In re Wada and Murphy*, Appeal 2007-3733, *citing In re Ochiai*, 71 F.3d 1565, 1572 (Fed. Cir. 1995) (emphasis in original). Thus, "obviousness requires a suggestion of all limitations in a claim." *CFMT, Inc. v. Yieldup Intern. Corp.*, 349 F.3d 1333, 1342 (Fed. Cir. 2003) (citing *In re Royka*, 490 F.2d 981, 985 (CCPA 1974)).

As discussed above, Mulye et al. neither teach nor suggest the step of pre-mixing at least one fatty acid salt with at least one layer silicate, prior to addition of the same to an aqueous suspension of film-forming polymer(s). Similarly, nowhere in the teachings of Lofroth et al. do Applicants find a teaching or suggestion of the present method, including the distinctive pre-mixing step. Therefore, the combination of Mulye et al. and Lofroth et al. cannot render the present invention obvious.

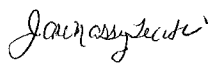
Applicants have found that the instant invention reduces deposition of the coating on the apparatus during spraying so there is no need to regularly clean the spray nozzle; eliminates agglomeration of pellets with no intermediate drying steps necessary; and achieves zero order release kinetics. Therefore, the specific way in which the coating excipients are mixed plays a fundamental role in determining the physical characteristics of the coating composition and the final pharmaceutical composition. Such effects are neither taught nor suggested by the combined teachings of the cited documents.

In addition, as discussed in paragraphs [0064] to [0065] of the present application, the coating *per se* is particularly suitable for an API having a high water-solubility (of more than 300 g/l, *e.g.* metoprolol, bisoprolol, tramadol, morphine, oxycodon and hydrocodon), despite the fact that it is a water-based dispersion. Such unexpected features are neither taught nor suggested by the combined teachings of cited references. Moreover, in so far as there is no indication in either of the cited references of the essential nature of the instant mixing regime that requires the fatty acid salt and the layer silicate to be pre-mixed prior to addition to the aqueous suspension of film-forming polymer(s), there would be no motivation for the skilled artisan to perform the claimed pre-mixing step; nor to believe that this would provide the afore-mentioned effects. Therefore, there is nothing in the combined teachings of the cited references to support an argument that the instant method would have been obvious. It is therefore respectfully requested that this rejection be reconsidered and withdrawn.

VI. Conclusion

Applicants believe that the foregoing comprises a full and complete response to the Office Action of record. Accordingly, favorable reconsideration and subsequent allowance of the pending claims is earnestly solicited.

Respectfully submitted,



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